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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,284	02/16/2001	John Ricci	1065.26 (B)	3054

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EXAMINER

BLANCO, JAVIER G

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 01/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/784,284

Applicant(s)

RICCI ET AL.

Examiner

Javier G. Blanco

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-7, 9 and 12-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-7, 9 and 12-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Objections

1. Claims 9, 14, and 18 are objected to because of the following typographical errors.
 - a. In claim 9, line 2, the expression “consisting hip, knee” should be written as “consisting of hip, knee”.
 - b. In claim 14, line 5, the expression “in a range of about of about” should be written as “in a range of about”. In line 8, the expression “promotion of rate, orientation” should be written as “promotion of the rate, orientation”.
 - c. In claim 18, line 3, the comma (“,”) after “plasma” should be deleted.
- Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claims 6, 17, and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
 - a. Regarding claim 6, an “orthonormal matrix” was not described in the specification.
 - b. Regarding claim 17, it recites that the ridges and grooves “are oriented transversely to said longitudinal axis of the implant”. Since claim 17 depends on claim 16, it does not make sense to orient the ridges and grooves parallel to the longitudinal axis of the implant (as claimed in claim

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16) and then orient them transversely to said longitudinal axis of the implant (as claimed in claim 17).

c. Regarding claim 19, the expression "comprises a product of the process" renders the claim vague and indefinite since it is not clear if by "product" it is referred to the geometric pattern, or, a part (area or component) of the geometric pattern.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

5. Claims 5, 9, 14, 18, and 19 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Branemark et al. (US 4,330,891). Branemark et al. disclose an element with a micro-pitted surface for growing tissue of a particular type. The pits or indentations have a cross-sectional configuration that is related to the size of a particular cell type in that the diameter is preferably no larger than the cell diameter of the application of use (see column 2, lines 37-44; 1000 nm= 1 micron). Column 5, lines 67-68 and column 6, lines 1-2, disclose some of those applications (i.e., joints) including hard bone tissue as well as soft tissue. The Abstract also

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discloses the element being extremely suitable as anchoring devices for a prosthesis and "may be made integral therewith". The base material of said implant consists of titanium and alloys thereof (see column 3, lines 55-61). A surface of the micro-pitted surface comprises a coating or "deposit of an agent facilitating and/or accelerating the growing process on or in the element" (see Abstract). The micro-pitted surface may be produced by mechanical etching (i.e., with a cutting tool; see column 4, lines 20-23).

6. Claims 5-7, 9, and 12-19 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Naiman et al. (US-5,607,607). Naiman et al. disclose an orthopedic implant comprising an implant element with a surface pattern as claimed in claims 1-13 (see Figures 4A-4H, 5A-5F, 6A-6E, 7A, 8, and 11; see whole text).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 5-7, 9, 14-16, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al. (US 4,778,469) in view of Mears (US 4,553,272). Lin et al. disclose the claimed invention except for any mention on the width or depth range of the ridges and/or grooves present in the surface pattern (repeat pattern 14) of the implant element (plate 10; see Figures 1-8; column 2, lines 36-60; column 3, lines 5-9, lines 13-15, and lines 53-63). However Mears teaches pores (i.e., grooves) sizes of about 25 microns in order to harbor cells and promote tissue

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growth or regeneration (see Figures 1-3; column 3, lines 48-59; column 4, lines 34-47; column 5, lines 34-40). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teaching of using pores/grooves sizes of about 25 microns, as taught by Mears, to the surface pattern of the implant element of Lin et al., in order to harbor cells and promote tissue growth or regeneration.

Response to Arguments

9. Applicant's arguments filed October 8, 2002 have been fully considered but they are not persuasive:

With respect to Branemark et al. '981, Applicants' argues that Branemark et al. range is "one-half of the low end of Applicants' range of dimension of parallel alternating ridges and grooves". Examiner respectfully disagrees. Given that a micron is such a small unit of length, 1.0 micron (1,000 nanometers) will fall in the range "of about 2 microns" as claimed in claim 14.

Also, Applicants argue that Branemark et al. do not teach a repetitive surface pattern of any type.

A dictionary search for the word "repetitive" defines it as containing repetition, repeating (duplicate or produce again). That definition applies to Branemark et al. "micro-pitted surface".

With respect to Naiman et al. '607, Applicants filed a Declaration under 37 C.F.R. 1.131 and an Expert Opinion under 37 C.F.R. 1.132. The inventive entity in Naiman et al. '607 is different from the inventive entity of the present application (09/784,284) and US 6,419,491. Also, the Declaration under 37 C.F.R. 1.131 and the Expert Opinion under 37 C.F.R. 1.132 fail to provide proof of conception and reduction to practice of the invention claimed herein prior to the effective filing date of Naiman et al. '607. The invention claimed herein is an orthopedic

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implant comprising an implant element having a micro-geometric, repetitive surface pattern of a multiplicity of alternating ridges and grooves with an established width of about 2 to about 25 microns, and an established depth of about 2 to about 25 microns. Said micro-geometric repetitive pattern defines a guide to promote the rate, orientation, and direction of growth of colonies of cells.

With respect to Lin et al. '469 in view of Mears '272, Applicants argue that "the lowest end of the range of Mears constitutes the upper limit of the range of the Applicants". Examiner respectfully disagrees. Mears' pore size range of 25 microns reads on the claimed range of "about 2 to about 25 microns". Also, a dictionary search for the word "repetitive" defines it as containing repetition, repeating (duplicate or produce again). That definition applies to Mears' implant porous surface.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Curtis et al. (US 5,833,641 A) and Singhvi et al. (US 5,976,826 A).

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

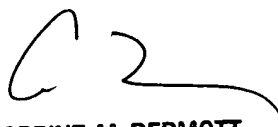
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 703-605-4259. The examiner can normally be reached on M-F (7:00 a.m.-4:30 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.


JGB

December 28, 2002


CORRINE McDERMOTT
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